DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/5/2011 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 2, 4-7 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nichols (US 3,088,466)** in view of **Jones (US 4,278,081),** further in view of **Toy (US 3,511,243).**

Regarding claims 1, 2 and 4-7, Nichols discloses a supporting device capable of supporting insertion of a medical instrument into a human body, comprising: a tubular member (1) includes a tubular member engagement section (15), the tubular member further includes an inner passageway between its opposite ends through which the medical instrument is capable of passing, wherein the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape (Figure 1) in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx; a guiding member (3) configured to guide the tubular member and the reinforcement member, the guiding member includes a guiding member engagement section (13) and the guiding member has a diameter smaller than that of the inner passageway, and when inserted from an oral cavity into the pharynx and retained there, the tubular member can guide the medical instrument to the digestive organ through the inner passageway, and such that when the guiding member engagement section is engaged with the tubular member engagement section, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member (column 4, line 71-column 5, line 5), but fails to disclose the tubular member having a slanted distal end, containing a reinforcement element, a second guiding member and the diameter of the tubular member being greater than 20mm.

However, Jones teaches a tubular member with a slanted distal end, (Figure 2) molded to contain a spiral reinforcement element (70) therein that extends within the

inner passageway along a longitudinal centerline, but does not extend past the distal end of the tubular member (column 7, line 66-column 8, line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tubular member having a slanted distal end and including a spiral reinforcement member to support the patency of the lumen of the tubular member, while still allowing a degree of flexibility, while reducing pressure at the distal end of the device (column 8, lines 3-7; the slanted end does not exert pressure 360° within the tubular organ at the distal end, thus relieving the pressure at that end).

Toy teaches a first guiding member (2) and a second guiding member (14) and a tubular member (10) that fits over the first and second guiding members (Figures 7-9), wherein the tubular member diameter is greater than 20mm (column 3, lines 45-48; 2 inches is approximately 50mm).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use two guiding tubes to provide a gradual expansion of the lumen in which the device is placed (column 3, lines 20-31). The initial insertion of first guiding member (2) would dilating the lumen to a first diameter, second guiding member (14) would slightly enlarge that diameter and finally the tubular member would be the largest in diameter, fitting over both the first and second guiding member to enlarge the lumen to the final diameter.

The prior art of record does not specifically disclose the device being used to dilate a pharyngeal lumen, but it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate

the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987). The devices disclosed in the prior art have the structural capability of being used to dilate a pharynx. The dual guiding tubes disclosed by Toy are used to gradually dilate an opening in a body lumen. Toy further discloses a third element (24; also including a distal end is that is slanted with respect to the center line of the device) that could be used as a guiding member. The use of the device disclosed in prior art does not have to be exactly the same as in the present invention, so long as the structure of the device can perform the claimed tasks.

Regarding claim 10, Nichols as modified above discloses the tubular member and the guiding member made of a variety of materials (column 1, lines 34-50), but fails to specifically disclose the guiding member made of a resin material harder than that of the tubular member.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the guiding member of a resin material harder than that of the tubular member, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

In response to applicant's argument that the prior art is used in a trachea while the present invention is to be used in a pharynx, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The way the devices of the prior art are described as being used in their respective disclosures does not disqualify the devices of the prior art from being manipulated to be used in the way described in the present invention. The structures disclosed in Nichols, Jones and Toy can be used in a manner as described in the currently presented claims. It is acknowledged that the methods of use of the device of the present invention and the prior art differ, however, the claims currently presented are drawn to the invention of the apparatus, thus the manner in which the devices are used is not the subject matter being examined..

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Szpira whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Friday, 10AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to:

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./
Examiner, Art Unit 3731
July 18, 2011

/S. Thomas Hughes/
Supervisory Patent Examiner, Art Unit 3731